EXHIBIT D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO PLAINTIFFS:	
Karen and Joel Forester 2:12-cv-00486	
Melissa and Charles Clayton 2:12-cv-00489	
Bonnie Blake and Larry Miketey 2:12-cv-00995	
Cherise and Marty Springer 2:12:cv-00997	
Angela and Bradley Morrison 2:12-cv-00800R	

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ORAL DEPOSITION OF
MELVYN A. ANHALT, M.D.
APRIL 2, 2016

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ORAL DEPOSITION OF MELVYN A. ANHALT, M.D., produced as a witness at the instance of the DEFENDANTS, and duly sworn, was taken in the above-styled and numbered cause on the 2nd of April, 2016, from 7:59 a.m. to 11:35 a.m., before Tamara Vinson, CSR in and for the State of Texas, reported by machine shorthand, at Hilton Houston Westchase, 9999 Westheimer Road, Ambassador Room, Houston, Texas, 77042, pursuant to the Federal Rules of Civil Procedure and the provisions stated on the record or attached hereto.

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ALSO PRESENT:

Ms. Tamara Vinson, Court Reporter

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mesh, are they?

A. No.

Q. Okay. And then on, I believe it might be four pages into your CV where it says Research. It's right after Work History.

A. Yes.

Q. You have four items listed under Research?

A. Yes.

Q. Are any of those related to pelvic mesh products?

A. No.

Q. Okay. That's all I have with respect to your CV, Doctor.

(Exhibit No. 4 marked.)

Q. The court reporter has handed you what has been marked as Exhibit No. 4.

A. Yes.

Q. Do you recognize this?

A. Yes.

Q. And what is this?

A. It's a list of articles that are journal articles or written things about TVT and TVT-Secur and a variety of incontinence-related things and prolapse and vaginal vault prolapse and cystoceles,

Transobturator and a variety of different journals.

Q. Okay. Is this the reliance list or materials that you relied upon with respect to your report?

A. These are articles that I have seen summaries of or I have read. I have subscribed to a thing that relate -- I put in what I'm interested in and every time there's an article that appears in any journal I get a summary of it. It's called Medscape.

Q. Medscape the thing that you said you subscribe to?

A. Yes, ma'am.

Q. Okay.

A. And so many of these I've read the summary, I've read the purpose of the article, but I haven't read the entire article. Some of these I have.

Q. Okay.

A. Most of what I relied upon was my experience.

Q. Your personal experience --

A. My personal experience.

Q. Just wait until I finish. I'm sorry, Doctor.

A. I'm sorry.

Q. Your personal experience in your care and treatment of patients?

A. Yes, ma'am.

Q. Okay. And the articles that are cited in here, are these all articles that you have come to know through the Medscape service that you subscribe to?

A. Most of them.

Q. Okay. Are any of the articles articles that the lawyers have provided to you?

A. You know, I haven't gone over this list in its entirety. I've pulled up the Medscape, went through that, and I can't tell you that there's not one or two that they added to it, because I haven't gone back and reviewed every one of these articles.

Q. Okay.

A. Okay. So the answer is I don't know.

Q. That's fair. You had mentioned that you subscribe to Medscape and you put in what you want -- I think you said what you want to search for?

A. Yes.

Q. And do you -- do you have it set up so that it sends you a periodic alert if there is a new article on a topic of interest to you?

A. Almost every day.

Q. Okay. And in what --

A. It comes on my cell phone.

Q. And were those cadaver labs, did they cover both prolapse and incontinence products?

A. In the beginning they were just incontinence. And the last one I went to, as I recall, was Prolift.

Q. And the incontinence products would have included TVT?

A. And TVTO.

Q. And what was your role?

A. The initial role was just to go there for my own education. I went several times to cadaver labs just for -- where I was not -- they had somebody who was considered to be a reasonable expert who was at each cadaver and so there were groups of doctors that were assigned to each cadaver. And so I went multiple times just for my own benefit, my own education, and then towards the end at least once that I recall I was -- I was in charge of one cadaver and we had, like, three other doctors and we would dissect the cadaver.

Q. Did you also do any speaking engagements or speeches on behalf of Ethicon at medical education programs?

A. Negative.

Q. So I just want to make sure I have a good

history of some of the work you did with Ethicon. You served on an advisory board once. Is that correct?

A. (No response.)

Q. And you did some didactic training?

A. Correct.

Q. And you were a preceptor?

A. Once.

Q. And you also did some work at the cadaver labs?

A. Yes.

Q. Okay. And you did participate in a product review meeting. Is that correct?

A. Only -- I've never been in a product review meeting, except the one meeting I had with the scientist that I was asked to meet with the scientist and that was to talk about the products we were using and how they could be improved.

Q. Is that --

A. It was not a scientific meeting. It was they wanted our clinical impression about that. I don't know -- I'm not a scientist. I'm not a materials person. I'm a -- I'm a practicing physician. I only care about how does it work for me.

Q. Got it. And so when you say with a

scientist, is that the same as the advisory board meeting?

A. No.

Q. So those are two separate meetings?

A. The advisory board meetings were where we met only with other physicians.

Q. Okay.

A. That was what I was describing to you earlier where they were divided up into groups of physicians at random and they would give us topics for us to discuss and then present to the general thing so everybody could stand up and say I've never had that happen or here's how to prevent that from happening or -- and discuss all aspects of TVT and subsequently Prolift.

Q. Okay.

A. So I don't consider that an advisory committee. I consider that an annual meeting that they were given the opportunity to meet with doctors from all over the country and find out what's happening in different places.

Q. Okay. Are you familiar with the phrase key opinion leader?

A. I've heard it before.

A. Yes.

Q. And you said you had the opportunity to watch another doctor perform, I think you said several cases. When you say cases, is that procedures?

A. TVT procedures.

Q. And you -- and that was over the course of two days?

A. Yes.

Q. And so that was -- do you think that was several different procedures?

A. Oh, it was all -- it was all the same procedure.

Q. Okay.

A. It was all TVT.

Q. Several different patients?

A. Correct.

Q. Okay. And did you have -- and that would have been the didactic training?

A. Well, the only didactic was he talked about the procedure and then he answered my questions.

Q. Okay.

A. And there were a couple other doctors there besides me, but I don't remember who they were.

Q. Sure. And this would have been in the early

2000s?

A. Yes.

Q. Okay. All right. And you had mentioned just a couple minutes ago that you're not a scientist and you're not a materials person, your focus is on treating patients. Correct?

A. Correct.

Q. Okay. And have you ever participated in the design of a pelvic mesh sling?

A. No.

Q. Okay. Have you ever done any bench research with respect to polypropylene mesh?

A. No.

Q. Have you ever done any lab research with respect to polypropylene mesh?

A. No.

Q. Have you ever done any work with respect to preparation of labels for medical devices?

A. No.

Q. Have you done any work with respect to drafting warnings with respect to medical devices?

A. No.

Q. Have you done any work with respect to drafting instructions for use for medical devices?

A. No.

Q. Okay. And when I say medical devices, I'm also -- do you understand that that would also include female pelvic mesh?

A. Yes.

Q. Okay. Have you ever participated in drafting training materials for other physicians with respect to pelvic mesh?

A. No.

Q. Have you ever prepared a device history file?

A. I don't even know what that means, so apparently not.

Q. Okay. Have you participated in drafting any documents regarding risk analysis with respect to the design of pelvic mesh products?

A. No.

Q. Have you ever been a consultant to the FDA?

A. No.

Q. You've never been employed by the FDA, have you?

A. No.

Q. Okay. Have you ever served on an FDA advisory board?

A. No.

Q. Have you had any correspondence with the FDA with respect to pelvic mesh products?

A. Well, I got the same letter that everybody got in regards to the FDA warnings.

Q. And when you -- you mentioned the same letter, you're talking about the public health notifications?

A. Yes, ma'am.

Q. Specific to pelvic mesh products?

A. Yes.

Q. Okay. Have you sent any communications to the FDA with respect to pelvic mesh products?

A. No.

Q. Okay. Have you ever had to submit any adverse event reports to the FDA regarding pelvic mesh products?

A. No.

Q. Have you ever done any presentations with respect to transvaginal mesh?

A. How do you define presentations?

Q. Perhaps where you were presenting a paper or you're doing a speech to a large group of other doctors, for example.

A. The only doctors that I've ever done that to

were the doctors who came to watch me do a Prolift.

Q. Okay.

A. One or two doctors at a time, but that's the extent of my -- I've never given a large group or I've never given a talk to a large group.

Q. Okay.

A. I was invited at one time -- this was years ago, maybe 2003, for Prolift to talk to the Dallas Urological Society about my experience with incontinence.

Q. Okay.

A. That was the only group that I've ever spoken to and we talked at that time about all the different techniques for incontinence procedures and my experience up to that point with TVT.

Q. And I'm sorry. Who had invited you to that -- the presentation?

A. A doctor from Dallas, a urologist.

Q. Doctor from Dallas, okay.

A. He was president of the Urological Society at the time and invited me to come speak.

Q. And did you do -- go ahead and do that?

A. I did.

Q. Okay.

Q. Okay.

A. If the leak point pressure is exceedingly low, then I think the regular TVT is a better procedure.

Q. Why is that?

A. Because it puts a little more pressure on the bladder neck because of the angle of where the mesh is, it's pulling the bladder neck a little tighter. And when you have an incompetent bladder neck, you need it to be a little tighter.

Q. And so is it fair to say that you would limit your use to TVT to those cases in which you had --

A. Incompetent bladder neck.

Q. -- incompetent bladder neck? Okay.

Have you published any papers on non-mesh treatment of stress urinary incontinence?

A. No.

Q. Do you have any unpublished papers with respect to non-mesh treatment of stress urinary incontinence?

A. No.

Q. Have you ever participated in -- well, strike that.

Are you familiar with the phrase "peer

review" as it relates to medical literature?

A. Yes.

Q. Have you participated in any peer review of others' articles with respect to stress urinary incontinence?

A. I was asked to serve on a peer review thing with the journal Urology at one time but I turned it down.

Q. Okay.

A. So the answer is no.

Q. Okay. Have you been involved in any clinical trials with respect to pelvic mesh products?

A. No.

Q. Okay. And so you have not done any clinical trial work comparing midurethral to other pelvic procedures?

A. No, not formally.

Q. Okay. Have you ever been involved in the clinical trial comparing pelvic or organ prolapse mesh repair to other types of pelvic procedures?

A. No.

Q. Are you currently working at any clinical studies?

A. No.

Q. Have you ever done any clinical studies of any kind?

A. Yes, we've done clinical studies related to some medications. Like when Proscar first came out, we did that. It's listed in my -- you'll see several medications where we participated in clinical studies.

Q. Okay.

A. They're listed.

Q. Yes. Have you done any clinical studies with respect to other types of medical devices?

A. No.

Q. Are you familiar with the phrase "ghost writing"?

A. Yes.

Q. Have you ever been asked to ghost-write an article --

A. No.

Q. -- for anyone else?

A. No.

Q. Have you published any articles with respect to porosity of mesh?

A. No.

Q. Have you published any articles with respect to degradation of mesh?

A. No.

Q. Okay. Have you published any articles with respect to flexibility or stiffness of mesh?

A. No.

Q. Do you hold yourself out to be an expert on FDA regulatory matters?

A. No.

Q. Do you have any specific expertise with respect to classification of medical devices at the FDA?

A. No.

Q. Do you have any expertise with respect to the way in which the FDA reviews products, mesh products, prior to placing them on the market?

A. No.

Q. Do you consider yourself an expert with respect to design controls on medical devices?

A. No.

Q. Do you consider yourself an expert with respect to design controls regarding the manner in which medical devices are manufactured?

A. No.

Q. Okay. Do you have any background in polymer sciences?

A. No.

Q. Do you consider yourself an expert on polymers?

A. No.

Q. Do you have any expertise with respect to biomaterials?

A. No.

Q. Do you consider yourself an expert with respect to biomaterials?

A. No.

Q. Have you done any bench research with respect to polypropylene?

A. No.

Q. Have you done any microscopic evaluation of explanted mesh?

A. No.

Q. Are you -- you are not a pathologist. Correct?

A. No. Correct.

Q. Do you have any expert --

A. Correct.

Q. Thank you. And you do not consider yourself an expert on pathology?

A. Correct.

Q. Okay. And you are not a toxicologist. Is that correct?

A. Yes, I am not.

Q. Thank you. And do you have any expertise in epidemiology?

A. No.

Q. Have you ever reviewed a pathological analysis of explanted mesh?

A. No.

Q. Have you reviewed any pathology reports with respect to explanted mesh?

A. Only what the -- in the few cases where I've removed some mesh, what the pathologist says about the mesh. That's all.

Q. Okay. And you don't do any separate analysis of that pathology?

A. No.

MS. FLAHERTY: Can we take just maybe a five-minute break and then we can move on to some of the next sections.

(Break.)

(Exhibit No. 5 marked.)

Q. (By Ms. Flaherty) Doctor, the court reporter has handed you what's been marked as Exhibit No. 5.

And just so the record is clear, this is a copy of the index card and business card you had provided earlier this morning. Is that correct?

A. Yes.

Q. And that is the card that we discussed that has the hours that you have spent reviewing some of the files.

A. Yes.

MS. FLAHERTY: Mark this one as Exhibit 6, too, please.

(Exhibit No. 6 marked.)

Q. (By Ms. Flaherty) And the court reporter has just handed you what's been marked as Exhibit No. 6 and your counsel provided this to us earlier this morning. Is this -- what is this document, Doctor?

A. Payment information.

Q. Okay. And does this exhibit appear to be a chart of the payments you have received from Ethicon over the years?

A. Appears to be, yes.

Q. Okay. We talked a little bit about your practice this morning and I may just have a few more questions for you about that. You had mentioned that currently your practice is roughly 50 percent women

and 50 percent men?

A. Yes.

Q. Okay. And with respect to the women, do you know what percentage of those women are coming to see you with respect to SUI, or stress urinary incontinence?

A. Well, you know, the overall percentage of women who have stress incontinence is in the 30 percent to -- has ranged anywhere from 30 to 40 percent of women. As they get -- I would say that of all the people that I see, maybe 15, 16 percent have stress incontinence.

Q. Okay.

A. That's significant.

Q. And that is significant incontinence?

A. That is significant symptom that we wanted fixed.

Q. Okay.

A. Many women have leakage, but they wear a pad and they don't care about having it fixed.

Q. Okay. The other 85 percent of the women that you treat, what types of conditions are you treating them for?

A. Urinary tract infections, kidney stones,

ureteral stones, bladder stones, bladder tumors, cancer of the kidney, cancer of the ureter, cystoceles, rectoceles, prolapse. I'm sure I'm leaving something off. Condyloma of the genitalia. I see occasional fistula, vesicle vaginal fistula, injuries to the bladder by the gynecologist. There's a whole host of things. I see people with blockage of the ureter from prior surgical procedures or from retroperitoneal fibrosis. It's a very complicated big list of things that bring women into the office at times.

Q. Okay. And I'm not going to hold you to this being an exhaustive list --

A. Right.

Q. -- but I wanted to get a feel for what the other 85 percent of your practice --

A. Right.

Q. -- was.

You had mentioned that roughly 15 percent of the women that come see you are coming to treat stress urinary incontinence.

A. Yes.

Q. And if I say SUI, do you understand that to mean stress urinary incontinence?

A. Acute pain -- whatever pain is, the patient who has the pain owns the pain. And so it's hard to distinguish between acute pain and chronic pain, and if they wake up and they say I've got some discomfort in my leg, they've got pain. If they say it hurts me to walk, they've got a little bit more severe pain. But in my experience, I've never had anybody that wasn't really transient. And most of the time transient is over -- by definition is less than three weeks.

Q. Okay. But you are aware that there have been some instances of the pain lasting for a longer period of time?

A. I've read that in the literature, yes.

Q. Okay. And would you agree that if they have what I'll call longer term or permanent pain, that that can have an impact on their quality of life?

A. Yes.

Q. With respect to dyspareunia, do you have an opinion as to whether or not that is transient or permanent in patients that have had a TVT or TVTO procedure?

A. I have had so few patients that have had dyspareunia with a TVT that it would be difficult for

me to judge transient. I've had maybe one or two, and both of those were somewhat transient.

Q. Okay. And are you aware that there have been reports of women who have had dyspareunia that is not transient following a TVT or TVTO procedure?

A. I am aware of it.

Q. Okay. So it is a possible risk?

A. Yes.

Q. And would you agree that having longer term or permanent dyspareunia would have an impact on one's quality of life?

A. Yes.

Q. Do you make any distinction between postoperative and chronic pain in patients that have had a TVT or TVTO procedure?

A. Yes. Well, chronic pain is long-term pain. Post-op pain usually subsides in a few days or a few weeks.

Q. And chronic pain would have an impact on a woman's quality of life?

A. Yes.

Q. Okay. And are you aware of any reports where women have developed chronic pain perhaps several months or longer after the TVT or TVTO procedure?

A. I've heard to that extent to some degree, but I haven't seen it.

Q. Okay. So you're aware of reports?

A. Yes.

Q. And it is possible?

A. I suppose it must be unless there's some other etiology. I mean, I have a hard time figuring out how that -- what the etiology of that would be or the mechanism of that. I always try to understand pain and I can't understand it.

Q. Would you agree that it can be a challenge to treat chronic or long-term pain?

A. Yes.

Q. Do you have any -- actually, strike that.

Would it also be a challenge to treat chronic dyspareunia?

A. Yes.

Q. Okay. Are you offering any opinions with respect to nerve damage associated with TVT or TVTO?

A. Well, my only opinion is that it would be a very -- a rare event. You would have to impact the obturator nerve to get nerve damage. As long as the -- you're going around the inferior pubic ramus, the only nerves in sight are -- and the obturator

foramina that the obturator nerve -- and unless the obturator nerve was impacted, I'm not sure how hugging the symphysis pubis on the regular TVT that I'm not aware of any nerves that sit on either side of the inferior pubic ramus. If you stray with a needle and you put it in a position where it's not supposed to be, I suppose you could find a nerve, but it would be an extremely rare event.

Q. Okay. But it is possible?

A. Yes.

Q. And that's one of the reasons why you had indicated your knowledge with respect to positioning of patients and your emphasis on the positioning of patients during the procedure is very important?

A. Yes.

Q. Would you make any distinction between neuromuscular and nerve damage?

A. Well, yes. It's hard to -- it's hard to distinguish between the two because nerve damage means that you -- nerve damage means that you damage the nerve. Neuromuscular means that as a result of mild trauma or inflammation to the nerve you have pain in the muscle. So I think that -- and if you'd ask ten doctors, you might get ten different answers about the

see in these women?

A. Most of the women that I've seen with complications is a failed sling. They're still incontinent.

Q. Okay.

A. Some of the other complications that I've seen is that I -- I think I've seen one or two that had mesh extrusion, that it was mesh was -- and one of them that I recall recently I didn't do her. It was somebody else that did her. She essentially was asymptomatic but her gynecologist felt a little bitty area of mesh exposure and she was about 80 and she was -- had a lot of atrophic vaginitis, lack of estrogen, so I put her on a little estrogen cream and that was it. She didn't need surgery.

Q. And she had mesh extrusion?

A. Yeah.

Q. Okay.

A. Well, exposure, extrusion are one and the same, aren't they? Is that in your mind? How do you define that?

Q. Well, I was just going to ask if you could define -- there's -- actually, strike that.

Doctor, would you agree that there are

different definitions for extrusion and erosion of mesh?

A. Yes.

Q. Okay. And how would you define extrusion?

A. I think it's just exposure of the mesh.

Q. Okay. And how would you define erosion?

A. Into an organ.

Q. Okay. Have you treated any women that have mesh erosion?

A. No -- well, yes, I have. I told you that earlier. I think I've had one -- one or two patients in which where -- in the TVT, not the obturator, but the regular in which there was -- they didn't recognize that the bladder had been perforated and there was mesh in the bladder. I think I told you that earlier this morning.

Q. Yes, I think you did. Thank you.

Have you -- are you aware of any women who have experienced degradation of their TVT or TVTO mesh?

A. No.

Q. Okay. Are you aware that there are reports of that happening in women that have had TVT --

A. I am aware --

Q. -- or TVTO mesh?
A. Yes, I am aware of that.
Q. Okay. So would you agree that it's a possible risk with respect to TVT or TVTO?
A. I don't really understand it because -- so I can't comment on it because I've never seen it.
Q. Okay. So you're not rendering any opinions with respect to what may cause degradation of mesh?
A. Correct.
Q. Okay. Are you aware of any reports of women that have -- have suffered bunching of their mesh?
A. I've seen it written in an article. I haven't seen it in any of my patients, but I've read an occasional report.
Q. Okay. Would you agree that bunching of the mesh is a risk of TVT or TVTO mesh?
A. I suppose it must be a risk because -- but -- but when you've done as many as I've done and you've never seen it, it can't be much of a risk.
Q. Are you familiar with the phrase roping of mesh?
A. Yes.
Q. And what is your understanding of roping?
A. Roping is where it -- when you pull on the

mesh, it unravels a little.

Q. Okay. Are you familiar with reports of TVT or TVTO roping?

A. No.

Q. Okay. Do you have any opinion as to whether or not roping is a risk of TVT or TVTO?

A. I just haven't seen it, so I don't have any opinion.

Q. Okay. Are you familiar with the phrase curling as it pertains to pelvic mesh?

A. Do you mean folding back? Is that what you're referring to?

Q. Yes, sir.

A. Yes, I am familiar with that.

Q. Okay. Are you aware that curling is a potential -- of the mesh is a potential risk with TVT or TVTO?

A. I haven't seen it but I'm aware that it's been reported.

Q. Okay. So you would agree that that is a risk with respect to TVT or TVTO?

A. It has to be a risk but I wouldn't consider it much of a risk.

Q. Okay. Are you familiar with the term fraying

as it applies to pelvic mesh?

A. Yes.

Q. Okay. And what is your understanding of fraying?

A. Fraying is where you -- it becomes stringy if you pull hard on the mesh.

Q. Okay. And do you have any opinions as to what causes the fraying?

A. The only time that I've ever seen fraying was a lawyer pulling on both ends of the mesh.

Q. And you don't have any opinions as to what might cause that mechanically?

A. You know, nobody pulls on mesh when you put it in the body, so I have a hard time understanding that that would occur.

Q. Are you aware of any reports of fraying occurring in women who have been treated with pelvic mesh?

A. I am not.

Q. Okay. Are you familiar with contraction as it relates to pelvic mesh products?

A. Yes, I am.

Q. Okay. And would you agree that contraction of mesh is a potential risk?

Q. Okay.

A. But everybody knows that there needs to be space between the mesh and the urethra.

Q. Okay. Do you -- we -- I don't think we've talked yet about mechanical or laser-cut mesh and we will talk a little bit about that shortly, but do you make any changes in how you tension the mesh based on mechanical or laser cut?

A. I've read a lot about it and I don't see much difference in my practice. I don't have a preference one way or the other. I'll use either one.

Q. Okay.

A. And I've had equally good results with both. I know from some of the meetings I've went to and some of the other doctors, this doctor, he'll only use laser cut. The doctor says I don't care, I'd just as soon have machine cut. So I don't -- I don't know that there's an absolute right answer to that. I personally don't distinguish between the two. I put both of them in and I have not had any ill results from doing that.

Q. Okay. And so just to clarify, you don't change how you tension the mesh based on laser versus mechanical cut?

A. I don't.

Q. Okay. You had testified earlier, I believe, that you have not reviewed any internal documents from Ethicon. Is that correct?

A. Yes.

Q. So if they have any internal documents that talk about fraying or roping of the mesh, you would not have reviewed those?

MR. WEBB: Objection. Form.

Q. (By Ms. Flaherty) You can answer.

A. I have not reviewed them.

Q. Okay. Have you over the years had to treat any patients who have had chronic dyspareunia with respect to pelvic mesh or following implantation of pelvic mesh?

A. Define what you're talking about pelvic mesh.

Q. Well, a polypropylene pelvic mesh product.

A. Prolift and TVT or both or one or both?

Q. Well, why don't we break that down?

A. Okay.

Q. Have you had to treat any women who have had chronic dyspareunia from Prolift?

A. Yes, I have.

Q. Okay. And have you had to treat any women

who have experienced chronic dyspareunia following implantation of a TVT?

A. I have not.

Q. Okay. Are you -- but you are aware of women who have reported chronic dyspareunia following implantation of a TVT?

A. I've seen it written about.

Q. Okay. And so you have no reason to disagree that it's a possible risk?

MR. WEBB: Objection. Form.

A. Not having experienced it, all I can do is say that I've read about it.

Q. (By Ms. Flaherty) Okay. And what type of treatment have you used on women who have experienced chronic dyspareunia?

A. Sometimes physical therapy can be beneficial.

Q. Is that pelvic floor --

A. Yes.

Q. -- physical therapy?

A. Pelvic floor, you know, there are a lot of -- I think when you have somebody who has dyspareunia and you're dealing with people who have had implantations, it's not an uncommon phenomena for some of these individuals to have other factors that play a role,

such as interstitial cystitis. Some of the voiding dysfunction that I've seen in patients turned out to be interstitial cystitis. And I've treated dyspareunia in some of those patients by treating interstitial cystitis in those patients and their dyspareunia has gone away.

Chronic dyspareunia is a very complicated factor. It's not one single factor. You have to be very careful about how you approach those patients. You have to -- you have to take all consideration about voiding dysfunctions. You have to talk about whether they have pain when they pee, whether they have pain after they pee, whether they have pain during the time they pee. Have they had infections. You have to take all those into consideration.

So if you have eliminated all of these other factors and then you are dealing with just the dyspareunia, then I use pelvic floor physical therapy and sometimes I'll even -- there's even a doctor here in Houston who deals with that, chronic dyspareunia, and he is a -- he's a urologist -- I mean a gynecologist who that's all he does is deal with dyspareunia. And I may refer the patient to them.

In certain circumstances I've got -- I've

got -- seen a patient, it's not my patient originally, who had an implant and I don't even feel the implant. It's put in so well, I can't even feel the damn thing and yet she's complaining of dyspareunia. And so I sent her to this doctor and I think he's helped her, but I don't know what all he's done. But taking this mesh out, in my opinion, at that point would have been ridiculous because I can't feel it. It's so well put in and it's been -- tissue is so well -- you know, has healed so well that I can -- I can touch this tissue and she doesn't have pain.

So I think that chronic dyspareunia is a multifaceted problem and I don't -- I think yes, I think sometimes mesh can maybe cause it but other times I'm not sure that's the etiology of it.

Q. And would you agree that it is something that is complicated to treat?

A. It can be.

Q. Who is the doctor that you referred to in Houston that treats chronic dyspareunia?

A. I'm trying to think of his name right now. He's a gynecologist. If you hadn't asked me that I probably would have told you three minutes ago. If you -- if you want that name I'll try to scrape it up

for you and get it. And you can give me an e-mail address and I'll e-mail it to you.

Q. Okay. If you think of it during the deposition, let us know.

A. Okay.

Q. You can interrupt me.

A. I can see his face but I can't think of his name right now. I even taught him how to do TVTs and I can't remember his name.

Q. Have you over the course of your practice ever prepared an adverse event report or something that's sometimes called a MedWatch report with respect to a TVT or TVTO?

A. No.

Q. Have you prepared such a report with respect to any pelvic mesh product?

A. No.

Q. I believe you had mentioned previously that you had seen some pathology reports from removed mesh. Is that correct?

A. Yes.

Q. Have you sent any mesh for subsequent testing on degradation or any further follow-up pathology?

A. No.

Q. Okay. And you don't have any opinions with respect to the pathological aspects of removed mesh?

A. No.

Q. Okay. You had mentioned previously that you don't have a personal preference on mechanical versus laser-cut mesh. Is that correct?

A. Correct.

Q. But you had indicated that you're aware that doctors do have different views on mechanical versus laser cut?

A. Yes.

Q. Okay. And you're not an expert on the mechanical properties of mechanical versus laser-cut mesh. Is that correct?

A. That is absolutely correct.

Q. Okay. I don't think we talked about flaking. Are you familiar with the phrase "flaking" as it pertains to mesh?

A. Pieces flake off?

Q. Yes.

A. I have not seen it but I've heard about it.

Q. Okay. Are you aware of that as a potential risk of mesh?

A. I'm aware that it's been reported, but I'm

not aware of it that -- in 1,500 cases that I participated in and taught people how to do, I'm not aware that it's happened to me.

Q. Okay. So it hasn't happened to you, but you know others have reported it?

A. I've seen it reported.

Q. Okay. And you're not rendering any opinions with respect to what in the material may cause flaking?

A. I am not rendering any opinions on that.

Q. Okay. And you're not rendering any opinions with respect to what about the material may cause roping, are you?

A. No.

Q. Okay. And you're not rendering any opinions with respect to what with the material may cause fraying, are you?

A. No.

Q. Okay.

(Discussion off the record.)

A. Let me return this for just a second, please.

Q. Yeah, that's not a problem. Not a problem at all.

(Break.)

(The reporter read back the last question and answer.)

Q. Doctor, are you offering any opinions on whether any aspect of the design of the product causes fraying of the mesh?

A. No.

Q. And are you rendering any opinions on whether any aspect of the design of the product causes curling of the mesh?

A. No.

Q. Okay. And are you offering any opinions on whether any aspect of the design of the product causes bunching of the mesh?

A. No.

Q. Okay. And are you rendering any opinions with respect to any aspect of the design of the product that may be causing roping of the mesh?

A. No.

Q. Okay. During the training that you received from Ethicon, did they ever make any distinctions to you with respect to mechanical versus laser-cut mesh?

A. No.

Q. During the training that you had with Ethicon, did they ever make any mention of fraying?

A. No.

Q. Did they ever make any mention of curling of the mesh?

A. No.

Q. Did they ever make any mention of roping of the mesh?

A. No.

Q. I can't remember, and I apologize if I asked this already: During your training with Ethicon did they ever make any mention of flaking of the mesh?

A. No.

Q. Do you consider yourself an expert with respect to the material polypropylene?

A. No.

Q. Are you offering any opinions with respect to the reactiveness of polypropylene mesh?

A. No.

Q. Are you offering any opinions with respect to degradation of polypropylene mesh?

A. I haven't seen it, but, no, I'm not offering an opinion.

Q. Okay. Are you offering any -- actually, strike that.

Are you offering any opinions with respect to

the weight of polypropylene mesh?

A. No.

Q. Are you offering any opinions with respect to the porosity of polypropylene mesh?

A. No.

Q. Are you offering any opinions with respect to the flexibility or stiffness of polypropylene mesh?

A. No.

MR. WEBB: Well, you've got stuff in your expert report. Are you saying you have no opinions at all about that?

A. No, I -- well, my opinion is that I don't find -- I don't find it to be too stiff or -- I find it to be appropriate, but. . .

MR. WEBB: Well, listen to the question and answer her questions --

THE WITNESS: Okay.

MR. WEBB: -- what she's asking you, whether you have opinions about these things.

A. Well, my opinion is I don't have a problem with the way it is -- the way the mesh is at this point.

Q. (By Ms. Flaherty) Okay. And that's -- so you're saying that the flexibility or stiffness, you

have not experienced any problems with that in TVT or TVTO?

A. That's correct.

Q. Okay. And do you have any knowledge regarding the design of the TVT or TVT with respect to the pore size?

A. All I know about it is, is that in most of the considerations has been that the pore size is large pore but not too large. If you got too large, it wouldn't be effective. It's not a small pore, it's a large pore. And so I'm not a materials person. I'm a clinical person. And from a clinical point of view, I consider it to be a large pore mesh and it's been -- I've found it to be very effective in tissue integration.

Q. And you don't have any opinions with respect to the material aspect of the -- with respect to pore size from a materials aspect?

A. Correct.

Q. Okay. And you don't have any opinions that you're rendering here today with respect to the elements of the design that factor into the pore size of the mesh?

A. I do not.

Q. Okay. Have you from a clinical standpoint, have you done any work with the smaller pore mesh?

A. No.

Q. Okay. Have you -- do you have any knowledge regarding the difference in pore size between the Monarc mesh that you use and the TVT or TVTO?

A. I've just seen an article or two written about it, but I don't have an opinion on it.

Q. Okay. And you haven't participated in any studies regarding the pore size of mesh. Is that correct?

A. Correct.

Q. Okay. And you haven't authored any articles regarding pore size of mesh?

A. Correct.

Q. Okay. Are you offering any opinions with respect to the warnings that Ethicon put into the instructions for use for TVT or TVTO?

A. I don't understand the nature of your question.

Q. Sure. Do you have an opinion as to whether the instructions for use set forth the risks of a TVT or TVTO mesh procedure?

A. I find the warnings to be adequate.

Q. Okay. And is that based on the knowledge that you have gained through the various things that we talked about today, the -- the training that you received in Cincinnati and, I believe, in -- there was one other location, as well, and your training of other individuals?

A. You know, in addition to -- I think that a lot of this comes from things that I know as a physician. I've had -- I've had training in surgery. I originally started a heart surgery residency before I got drafted. I had two years in the Navy operating. So a lot of the warnings and a lot of the things are applicable to regular surgical procedures. Hernias that I used to do, gallbladders that I used to do, I know a lot about surgery. I know a lot about warnings.

I know about risk, and when I read the warning on an IFU I know what they mean when they talk about pain, I know what they mean when they talk -- the different things that are mentioned in the IFU. I know about how to tell the patient what the risks are, and so I don't depend on the IFU. I depend on what I know, what I've learned, what I've -- what other people have instructed me about it. So I don't have